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K964649

510(k) Summary

Device Proprietary Name: Vazquez-Diner Intraoral Distraction Device

Device Common Name: Mandibular Bone Distractor

Classification Name: Smooth or metallic bone fixation fastener
21 CFR 888.3040

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Summary:

This submission describes an intraoral distraction device. It is intended for use as a mandibular bone lengthener for patients diagnosed with conditions where treatment includes mandibular distraction osteogenesis. These conditions may include diagnoses such as mandibular micrognathia or hemifacial microsomia. The device consists of three major components: the threaded self drilling fixation pins, the mandibular distraction frame and the distraction rod and key. The pins attach the frame to the mandible. The distraction rod attaches to the frame and is rotated via the key to apply tension to the frame and osteotomy site. Directions regarding distraction are given to the patient by the physician. Frames are available for up to 18 mm or 28 mm of distraction depending upon the condition of the mandible. All components of this device are for single use.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Howmedica Mandibular Bone Lengthener (K945674), the Wells Johnson Fixation System (K945500), the Synthes Mini Lengthening Apparatus (K914558) and the Synthes Mandible Distractor (K962272). Each of these devices is intended for use as a mandibular bone lengthener and is manufactured from stainless steel. The designs are equivalent in that they include distraction frames which are attached to the mandible by means of fixation pins on either side of the osteotomy. The Howmedica Mandibular Bone Lengthener, the Wells Johnson Fixation System and the Synthes Mini Lengthening Apparatus are each external fixation systems while the Vazquez-Diner Intraoral Distraction Device and the Synthes Mandible Distractor are intraoral/subcutaneous fixation systems. The basic operational principle of distraction osteogenesis through controlled tensioning of the device construct and osteotomy site is similar for each of these devices.